

REMARKS

The Office Action dated November 21, 2007, addresses claims 1-24, rejecting all claims under 35 U.S.C. § 103(a) as being unpatentable over Martin et al. (U.S. Patent No. 5,368,594, "Martin") in view of Vignaud et al. (U.S. Patent No. 5,176,680, "Vignaud") and further in view of Schlapfer et al. (U.S. Patent No. 5,501,684, "Schlapfer"). In addition, the Examiner rejected claim 23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

By this response, claims 1, 6, 12, and 17 have been amended to present the subject matter with improved clarity. New claims 25-35 have been added to define additional aspects of the disclosure. No new matter has been introduced by this Amendment.

For all of the following reasons, Applicant respectfully requests reconsideration and early allowance of the claims as currently amended.

Claim Rejections under 35 U.S.C. § 112, ¶1

Claim 23 is rejected as failing to comply with the written description requirement of 35 U.S.C. § 112, ¶1. The Examiner asserts that the specification does not convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. Specifically, the Examiner alleges that the aperture of the cap, as disclosed in the specification, refers to element 17 as conical, not spherical.

Applicant respectfully traverses this rejection. The Examiner's attention is kindly drawn to FIG. 1, which illustrates an embodiment of the claimed invention. The aperture of cap 15, as depicted in FIG. 1, has a spherical cross-section, and therefore, it provides express support for the claimed limitation of "the aperture of the cap has a spherical cross-section..." as recited in claim 23.

For the above reason, Applicant respectfully submits that claim 23 is fully enabled, and would allow one of ordinary skill in the art to make or use the invention without undue experimentation. It is respectfully submitted that the rejection of claim 23 for lack of written description under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections under 35 U.S.C. § 103(a)

The Office Action rejects claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Martin in view of Vignaud and further in view of Schlapfer. The Examiner refutes the Applicant's arguments filed September 26, 2007, and maintains that the cited references render the claims obvious to one of ordinary skill in the art.

The Examiner alleges that Martin discloses each of the elements of the previously presented claims except that it does not disclose spherical lateral undercuts to allow pivoting, a ring placed along the pin, and a spherical cavity capable of securing the pin with a ring about it. The Office Action states that Vignaud discloses a similar device including a bone-anchoring portion (1), a split ring (9) slidable along the length of the spinal rod (6), clamping means (7, 8, and

18) and lateral undercuts (15 and 17), wherein the ring and the lateral undercuts allow pivoting of the spinal rod. The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Martin with the split ring and lateral undercuts of Vignaud to allow for placement of a rod in an orientation other than perpendicular to the pedicle screw in order to facilitate the positioning of the spine.

The Office Action further states that Schlapfer teaches a sliding ring to allow pivoting of the screw in a bone fixation device, the ring including alternating longitudinal cuts. The Office Action alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the split ring in the combination of Martin and Vignaud with the teaching of Schlapfer to allow greater flexibility of the spinal rod while maintaining integrity.

The Examiner further objects to the Applicant's prior argument that Martin and Vignaud fail to disclose or suggest a ring received within the cavity with snap on installation (as recited in claim 1), and a head having a cavity with a spherical contour (as recited in claim 12). The Examiner asserts that the combined teachings of both the references would enable one having ordinary skill in the art to achieve a snap-on installation utilizing a ring by appropriately designing the cavity to receive a spherical component.

Applicant respectfully traverses the rejection. To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Office must establish that some suggestion or motivation exists, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the references to achieve the presently claimed invention. See M.P.E.P. § 2143.01.

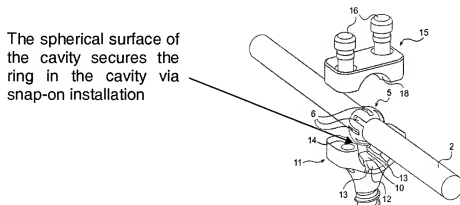
In page 5, ¶13, of the Office Action, the Examiner states that “all that has been gleaned from the Vignaud et al. reference in regard the Martin et al. reference was the teaching for allowing pivoting of the spinal rod to assist in re-establishing physiologic curvature.” However, the Examiner fails to acknowledge that neither Martin, nor Vignaud, either alone or in combination, suggest or disclose achieving snap-on installation of the pin on the screw using a spherical ring, which now by this amendment is expressly stated in claims 1 and 12. The snap-on installation allows the pin held by the ring to be secured to a screw while allowing continued angular mobility of the ring and the pin with respect to the screw, as other screws are placed or other aspects of a surgery are performed.

Martin discloses the concept of provisional attachment of the spinal rods to the bone anchoring elements to facilitate adjustment of the rod according to the curvature of the spine. However, as described in col. 4, l. 1 to l. 6, Martin achieves the temporary clamping of the rods 3 in the channels 11 by means of the projections 20 on the inside faces of lateral walls 10, or simply by the distance between the inside faces of lateral walls 10, at the upper ends, being smaller than the diameter of spinal rod 3. Martin does not disclose or suggest the use of a ring about the spinal rod to assist in securing the rod to the bone anchoring element.

Vignaud, on the other hand, does not disclose provisional attachment or snap-on installation of the pin to the pedicular screw at all. As describe in col. 2, l. 41 to l. 49, the locking screw 7 and the cap 8 are positioned in the space between the branches 4a and 4b of the diapason-shaped head immediately after the rod 6 is placed within the housing 5 of the screw, in order to secure the rod while angular adjustments are performed. That is, the ring 9 does not "snap-on" to the housing 5 of the screw, and instead requires two separate pieces to secure it in place. The sole purpose of the ring 9 is to facilitate angular movement of the rod with respect to the screw, and no suggestion exists within the reference to imply otherwise.

In contrast, claim 1 of the present disclosure, as currently amended, requires snap-on installation of the rod in the cavity that the head delimits by means of the spherical ring 5. As stated in paragraph [0021] of the present disclosure, the outer diameter of the ring is slightly larger than the spherical cavity 10, which allows the installation of the rod in the cavity in a "snap-on" manner, and prevents the rod from sliding out of the cavity in a direction along an axis of the rod by holding it firmly in the cavity. The slots on the periphery of the ring also facilitate the clamping of the ring in the cavity by permitting more radial flexibility to the ring. Further, as depicted in FIG. 1 of the present application, reproduced below, the spherical outer surface of the ring engages the spherical contour of the cavity, and thus provide secure installation of the rod in the cavity.

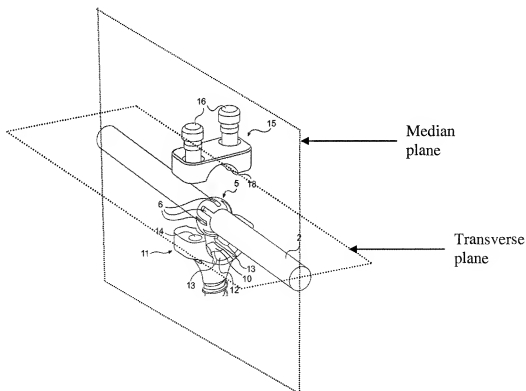
Such a secure attachment would not have been provided by a cylindrical rod, by itself, in a spherical cavity.



Thus, no motivation or suggestion exists to combine their teachings to achieve a snap-on installation utilizing a ring. The ring, in fact, serves the dual purpose of securing the rod in the cavity, and facilitating the angular mobility of the rod in conjunction with the lateral undercuts and the spherical contour of the cavity.

Further, claim 1 of the present application, as currently amended, recites that the shape of the cavity of each screw head allows angular mobility of the pin in multiple planes. The spherical contour of the cavity, as described in paragraph [0021], cooperates with the spherical ring to facilitate the angular mobility of the pin with respect to the screw prior to immobilization of the pin within the head of the screw. In addition, paragraph [0021] of this application discloses that the cavity is bordered by two lateral undercuts 12 in the form of a hollow sphere, that allow in the snap-on installation position of the ring, angular clearance of the pin

with respect to the screw. As illustrated in the figure below, the lateral undercuts would provide angular clearance to the pin for movement in both the median (vertical) plane and the transverse (horizontal) plane, and thus provide better alignment of the vertebral arthrodesis device. In contrast, Vignaud discloses angular clearance of the rod in only the median plane, which is referred to as the sagittal plane, through the recess 15 at the bottom of the housing 5, and the truncated section 16 of the locking screw 7. See Vignaud at col. 1, l. 35-40, and col. 2, l. 54-59. Mobility along the transverse plane would be clearly restricted by the branches 4a, 4b of the diapason-shaped head of Vignaud's device. Martin, on the other hand, does not disclose or suggest angular adjustments of the pin at all. Therefore, neither Martin, nor Vignaud, alone or in combination, disclose each and every limitation of claim 1 as currently amended.



Further, Schlapfer, which the Examiner appears to have cited only based on the structural features of the ring, does not disclose the snap-on installation of a ring about a rod within a spherical cavity, or angular adjustments of a rod in multiple planes, and therefore, does not cure the defect in the rejection based on Martin and Vignaud.

Therefore, it is respectfully submitted that the rejection of claim 1 be withdrawn for the above stated reasons. Claims 2-11 depend from claim 1, and thus are patentable over Martin, Vignaud, and Schlapfer for at least the same reasons as claim 1.

Claim 12 recites the limitation of "snap-on" engagement of a spherical ring in a spherical cavity, as similar to claim 1, and therefore, should be allowed for at least the same reasons as claim 1. In addition, since claims 13-24 depend from claim 12, the rejection of claims 13-24 under 35 U.S.C. § 103(a) should be withdrawn.

New claims 25-35 have been added. To the extent the rejection of claims 1-24 is applicable to these claims, Applicant provides the following comments.

Claims 25-35 disclose a method of vertebral arthrodesis, comprising the steps of providing a pin with a ring having a spherical outer surface disposed about it, snap-fitting the ring into one or more screws, adjusting the alignment of the pin along multiple planes prior to immobilization of the pin, and fastening a cap on the head of each screw overlapping the ring that is snap-fitted into the screw. Neither Martin nor Vignaud, alone or in combination, disclose a method of provisionally attaching an arthrodesis pin to pedicle screws by means of

spherical rings on the pin. The cited references also do not disclose a method of multi-angular adjustment of the pin with respect to the screws by providing spherical lateral undercuts on the head of the screws.

Applicant, therefore, respectfully requests consideration and timely allowance of these new claims.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the claims as amended.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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